

REMARKS

Claims 31, 33-49, 53, 55, 56, 59, 61-76, 80, 82, and 114-120 are pending in the application and stand rejected. With this response independent claims 31, 59, 114, 116-120 are amended. Upon entry of the amendments, claims 31, 33-49, 53, 55, 56, 59, 61-76, 80, 82, and 114-120 remain pending.

Support for the amendments to claims 31, 59, 114, 116-120 is found in the specification as originally filed, for example in paragraph [0024]. Paragraph [0024] describes a manufacturing process for preparing a core containing metformin. In the process, metformin is granulated with a binder, leading to a granulated core. Applicants respectfully request entry of the amendments.

REJECTIONS UNDER 35 U.S.C. § 103

Claims 31, 33-45, 47, 49, 53, 55, 56, 59, 61-72, 74, 76, 80, 82, 114, 115, and 117-120 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pub. 2003/0021841A1, Matharu et al., January 30, 2003 (hereafter *Matharu*) in view of U.S. Pat. 5,472,712, Oshlack et al., December 5, 1995 (hereafter *Oshlack*) and in further view of U.S. Pat. 6,592,900, Bühler et al., July 15, 2003 (hereafter *Bühler*) and/or Morita et al., J. Controlled Release 2000, 63, 297-304 (hereafter *Morita*). Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

The independent claims have all been amended to recite that the core is a “granulated” core. This feature of the amended claims is not disclosed or suggested in the primary reference, *Matharu*. Further, the secondary references cited (*Oshlack*, *Bühler*, and/or *Morita*) do not make up for the deficiencies of the primary reference (*Matharu*) as applied to the amended claims.

Matharu teaches away from providing tablets having a granulated core. For example, the reference states at paragraphs [0003] and [0004]:

[0003] One way to overcome the poor compressibility of pharmaceutical agents is to utilize wet granulation techniques to prepare the tablet formulation. This involves additional unit operations of wet milling, drying and milling of dried granulation (sic). However tablets prepared by wet methods often show incremental hardness as a functional time and storage temperature. Therefore, tablets prepared by wet methods are more likely to show variable product performance.

[0004] The object of the present invention is to prepare pharmaceutical tablets of poorly-compressible drugs that have adequate and stable hardness and good reproducibility, by a process that avoids wet granulation during processing.

The above passage from the primary reference shows that the teachings of the reference are not drawn to processes that produce granulated cores, as in the amended claims.

Matharu, and in particular passages such as those cited above, thus teaches away from providing granulated cores for an extended release pharmaceutical tablet as recited in the amended claims. The secondary references do not make up for those deficiencies. In particular, they do not contain a teaching or suggestion to use a granulated core comprising metformin in an extended release pharmaceutical tablet. For these reasons, Applicants respectfully request the rejection be withdrawn.

Claims 31, 33-49, 55, 56, 59, 61-76, 82, and 116 stand rejected under 35 U.S.C. § 103(a) as obvious over *Matharu* in view of U.S. Pat. 4,892,742, Shah, January 9, 1990 (hereafter *Shah*), and/or *Oshlack* in further view of *Morita*. Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.


The deficiencies of *Matharu* as applied to the independent claims 31, 59, 114, 116-120 are discussed above. Applicants respectfully submit that *Shah*, *Oshlack*, and *Morita* do not overcome those deficiencies. For these reasons and the reasons discussed above, Applicants respectfully request the rejection be withdrawn.

CONCLUSION

For the reasons discussed above, Applicants believe that claims 31, 33-49, 53, 55, 56, 59, 61-76, 80, 82, and 114-120 as amended are in an allowable condition and respectfully request an early Notice of Allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

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